GENERAL REVIEW AND ENFORCEMENT POLICIES

INITIAL PROCESSING OF AN NADA

1. Purpose:

This guide sets forth the procedures for receipt and initial processing of a New Animal Drug Application (NADA).

2. Authority:

a. Section 512(b) of the Federal Food, Drug, and Cosmetic Act (FFDCA) sets forth the broad requirements for the content of an NADA.

b. Section 512(c) of the Act requires the Agency to take an appropriate action within 180 days after the filing of an NADA.

c. 21 CFR 514.1 provides the outline for the organization and content of an NADA.

3. Initial Processing of an NADA:

a. An original NADA is received in Document Control Unit (HFV-199), where it will be date stamped, prepared for review and assigned to the appropriate division as described in Guide 1240.2120 Product Manager.

b. The NADA will be sent to the review Division, along with a draft letter acknowledging receipt and assigning the NADA number.

c. The responsible reviewTeam within the Division will immediately perform a cursory review of the NADA to determine if it is acceptable for filing. The criteria for this determination are found in 21 CFR 514.11 Reasons for Refusing to File Applications. Briefly, these are:

(1) It does not contain complete and accurate English translations of any pertinent part in a foreign language.

(2) Fewer than three copies are submitted.

NOTE: The regulations for submission of a New Drug Application for human drugs provide for two copies, a complete archival copy and a review copy with separate technical sections for each major data group. Since CVM is proposing the same format for NADAs, we are accepting NADAs submitted in this format. See 21 CFR 314.50 and the proposed section 514.50 for details.

(3) It is incomplete on its face in that it is not properly organized and indexed.

(4) On its face, the information concerning required matter is so inadequate that the application is clearly not approvable.

NOTE: An NADA is required to contain complete reports of investigations to show whether or not a drug is safe and effective for use. If such reports have previously been submitted, either in a related NADA or in the INAD through the phased review process, this requirement is considered to be met if each affected section of the NADA contains a specific reference to where the reports may be found.

(5) The manufacturing establishment where the drug is to be produced is not registered or exempted from registration.

(6) The applicant does not reside or maintain a place of business in the United States and the application has not bee counter-signed by an authorized United States agent.

(7) The drug is regulated by USDA under the Virus, Serum and Toxin Act of 1913.

NOTE: Some products, especially those produced by modern biotechnology, may fit under either the FFD&C Act or VSTA. In such cases, a standing committee comprised of FDA and USDA officials will determine jurisdiction over the product. In the event an NADA for such a product is received, it should immediately be referred to the Director for Surveillance and Compliance, the CVM liaison to the Committee (See Compliance Policy Guide 7155a.17.)

(8) The application fails to include, with respect to each non-clinical laboratory study contained in the application, either a statement that the study was conducted in compliance with the GLP regulations in 21 CFR Part 25, or, if it was not, a brief statement of the reasons for noncompliance.

(9) The application fails to contain an environmental assessment or fails to provide support for a request for categorical exclusion (See 21 CFR Part 25.)

d. If acceptable for filing, the Division Director will initial the draft acknowledgement letter, and return the file to HFV-199 where the letter will be signed and issued.

e. If not acceptable for filing, the reviewTeam will prepare, for the Division Director's signature, a letter refusing to file the application. The letter will enumerate the reasons for refusal to file, and will advise that the application is being retained by FDA pending receipt of the necessary information, or receipt of a written request that the application be filed over protest. This letter should issue within 30 days of receipt of the application.